UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,938	05/15/2006	Marvin J. Fritzler	66609.1US	8610

24286 7590 02/08/2007

WILLIAM J BUNDREN
THE LAW OFFICE OF WILLIAM J BUNDREN
734 LaRue Road
Millersville, MD 21108

EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,938	FRITZLER, MARVIN J.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *3 and 5-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Specie 2 (claims 2 and 5) in the reply filed on 18 December 2006 is acknowledged. The traversal is on the ground(s) that all of the monoclonal antibodies function the same as each binds to GW 182. Applicant also argues that because at least two separate inventive concepts are disclosed in claims 1 and 8, any species that read upon these concepts are deemed to form a single inventive concept. This is not found persuasive.

PCT Rule 13.1 allows ONE inventive concept and any inventions that relate to the SAME inventive concept may be grouped together. The inventive concept in this case is a monoclonal antibody to GW 182. At least two different inventions relating to a single inventive concept, claims 1 and 8, are disclosed and will be examine together; however, each of the monoclonal antibody is a different species of the general inventive concept and thus, restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:

3. The inventorship of the provision application is not the same with that of the instant application. Correction is required.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to provide an adequate written description of the invention and fails to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are: (1) known and readily available to the public; (2) reproducible from the written description; or, (3) deposited in compliance with the criteria set forth in 37 CFR §§ 1.801-1.809.

The specification lacks complete deposit information for the monoclonal 2D6. Because it is not clear that the cell line possessing the properties of the hybridoma designated 2D6 is known and publicly available or can be reproducibly isolated without undue experimentation, and because the invention of claims 2 and 4 claims or uses the monoclonal antibody, a suitable deposit for patent purposes is required. Accordingly,

filing of evidence of the reproducible production of the cell lines and antibodies necessary to practice the instant invention or filing of evidence of deposit is required. Without a publicly available deposit of the above cell lines, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell lines is an unpredictable event. Applicants must comply with the criteria set forth in 37 CFR §§ 1.801-1.809.

If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific cell lines have been deposited under the Budapest Treaty, that the cell lines will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and that the cell lines will be replaced should they ever become non-viable, would satisfy the deposit requirement made herein.

If the deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR §§ 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
2. All restrictions upon availability to the public will be irrevocably removed upon

granting of the patent;

3. The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
4. The deposits were viable at the time of deposit; and,
5. That the deposits will be replaced if they should ever become non-viable.

For each deposit made pursuant to these regulations, the specification shall contain:

- The accession number for the deposit;
- The date of the deposit;
- A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- The name and address of the depository.
- Any amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section must be filed before or with the payment of the issue fee.

In the instant case, the specification is silent with respect to the deposit information.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit along with the necessary statements in order to meet the criteria se forth in 37 CFR §§ 1.801-1.809.

Applicant's attention is directed to In re Lundak, 773 F.2nd. 1216, 227 USPQ 90 (CAFC 1985) and 37 CRF □1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague because it currently recites non-elected species. Specifically, the non-elected monoclonal antibodies 4B6, 5C6 and 6D7.

Claim 4 lacks deposit information.

Claim 8 is vague with respect to the "assaying" step. It is unclear what is involved in this step and how it relates to the preamble of the claim. Claim 8 is also confusing with respect to the recitation of "a monoclonal antibody of claim 1", lines 2 and 3. It is suggested that "a monoclonal antibody" be changed to -the monoclonal antibody— for clarity.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (f) he did not himself invent the subject matter sought to be patented.

9. Claims 1, 2, 4 and 8 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

A publication by Eystathioy et al., (*Hybridoma and Hybridomics*. 2003. 22(2):79-86) discloses the same monoclonal antibody, 2D6 and method using it to detect GW 182 in serum sample. See abstract.

The authorship of this paper differs from the inventorship of the instant application, therefore, it is unclear whether applicant invent the claimed subject matter.

10. Claims 1, 2, 4 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Eystathioy et al (*Hybridoma and Hybridomics*. 2003. 22(2):79-86).

Since priority is not given back to the provisional application 60/440,326, the filing date of the instant application is 16 January 2004.

Eystathioy discloses the invention exactly as claimed. See abstract.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eystathioy et al (*Molecular Biology of the Cell*. April 2002. 13:1338-1351) in view of Kohler (*Science*. 1986. 233 (4770):1281-1286).

Eystathioy fully discloses GW ribonuleoprotein including a 182kDa protein designated GW182 and rabbit and human serum binding to the same.

Eystathioy differs in failing to specifically teach monoclonal antibodies to GW 182.

Kohler disclosed a method for producing hybridoma cell lines secreting monoclonal antibodies using lymphocyte fusion techniques. Kohler disclosed that polyclonal antibodies suffers from major disadvantages such as low titers, the polyclonal antibodies are heterogeneous, limited supply and that it is impossible to reproduce the same combination of specific antibodies in a new animal. In contrast, lymphocyte fusion provides the advantages of specificity, unlimited supply of antibody. The use of impure antigens still leads to pure antibody reagents. All specificities can be rescued. Enrichment or specific hybridomas is possible. A high

level of antibody secretion is observed. The hybridoma cell lines can be manipulated to product antibodies not found in nature, and the method is general such that antibodies against any antigen may be produced. See page 1281.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a monoclonal antibody against the protein taught by Eystathioy using the method of Kohler because Kohler teaches that any substance that can elicit a humoral response can be used to prepare monoclonal antibodies, and that monoclonal antibodies provides advantages not found in polyclonal antibodies. These advantages include specificity of binding, homogeneity, and ability to be produced in unlimited quantities. The production of monoclonal antibodies allows the isolation of reagents with a unique and chosen specificity. Because all of the antibodies produced by descendants of one hybridoma cell are identical, monoclonal antibodies are powerful reagents for testing for the presence of a desired epitope. In addition, one unique advantage of hybridoma production is that impure antigens can be used to produce specific antibodies. A skilled artisan would have had a reasonable expectation of success and would have been motivated to use the techniques of Kohler to produce monoclonal antibodies to the GW 182 protein taught by Eystathioy because such techniques are well known in the art and provides advantages not found with polyclonal antibodies.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 1/31/07